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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,217	12/03/2003	Mark B. Chidlaw	PC9858A	4494
28523	7590	09/10/2007	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			09/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,217

Applicant(s)

CHIDLAW ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/26/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-13, 15-18, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cardinal et al. US 5,612,059.

Cardinal discloses a controlled release device comprising an active core and one or more asymmetric membranes (abstract; column 10, lines 26-63; and claims).

Asymmetric coating comprises cellulosic material including cellulose acetate (column 7, lines 45-67; and claims 19-28). Active comprises drugs (column 10, lines 18-25).

Cardinal further discloses controlled release of active substance is by diffusion and/or osmotic pumping (abstract; column 9, lines 20-65; and column 10, lines 52-57).

The claimed properties, such as dietary fat in the use environment, and time to release 50% of the active agent into the use environment is at least 0.5 fold, but less than 2.0 fold the time required for the composition to release 50% of said active agent into a control use environment comprising less than about 0.1% dietary fat, are silent. However, Cardinal teaches the use of the claimed polymeric coating, *e.g.*, cellulose acetate as an asymmetric membrane for a controlled release of active agent to the same use environment, oral administration. Accordingly, the use identical structures being administering to the same environment of use necessitates similar properties

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desired by the applicant. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). When the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

Claims 1-7 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al., in view of Faour US 6,004,582.

Cardinal is relied upon for the reason disclosed above. Cardinal does not teach the claimed active agent. Cardinal further does not teach the taste mask and the immediate release coatings.

Faour teaches a process for preparing an osmotic dosage form comprising an active core **(5)**, a semipermeable membrane **(4)**, a water-soluble polymer coat **(3)**, and an immediate release active agent-containing external coat **(2)** (column 4, lines 63 through column 6, lines 1-13; and Fig. 2). The claimed active agents can be found in columns 13-15). Faour further teaches the dosage form is suitable to deliver one or more active agents to an environment of use in a controlled manner (abstract; column 1,

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lines 4-22; and column 5, lines 1-3). Semipermeable membrane includes cellulose acetate and polyethylene glycol (column 4, lines 24-34; column 9, lines 1-27; and examples). Faour further teaches a taste masked finish coating **(8)** (column 17, lines 58-64; and examples). Thus, it would have been obvious to one of ordinary skill in the art to modify the osmotic device of Cardinal to include an immediate release and a taste mask release coatings in view of the teachings of Faour, because Faour teaches an improved osmotic device that overcomes many of the disadvantages inherent in related prior art devices (column 3, lines 29-39), because Faour teaches an osmotic device that provides a broader range of independent release profiles for one or more active agents (id), because Cardinal teaches a controlled release device suitable for a wide variety of active substances, and because Cardinal teaches the desirability of obtaining an osmotic device to control the release of one or more active substances into an environment of use (column 4, lines 18-26).

Claims 8 and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al., in view of Faour US 6,004,582 and, FDA press release or Camden US 6,136,835.

Cardinal is relied upon for the reasons stated above. Cardinal does not expressly teach a dosage form with a written matter indication.

FDA press release teaches an improved package inserts that include boxed warning, indications and usage, and dosage and administration (page 2). FDA press release further teaches the improved package inserts provide safe an optimal use of

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drugs, which improves health outcomes for patients and more efficient delivery of healthcare (page 1).

Camden teaches a pharmaceutical composition comprising a container, a dosage form, and a printed instructions either as an inserts or as labels, indicating quantities of the components to be administered, guidelines for administration (column 20, lines 1-15).

Thus, it would have been obvious to one of ordinary skill in the art to prepare a dosage form that includes a written indication to provide guideline for administration, because it is required by the FDA, and because it is well known in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 06/26/07 have been fully considered but they are not persuasive.

Applicant argues that Faour does not teach asymmetric coating.

However, in response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Faour is cited for the suggestion that osmotic device can include immediate release and/or taste masking coatings.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 06/26/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUSAN TRAN
PRIMARY EXAMINER

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